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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,918	06/13/2001	Gordon W. Glazner	84894-602	2276

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/878,918	GLAZNER, GORDON W.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/2006 has been entered.

Claim(s) 1-5, 7-31 have been cancelled. Claim(s) 6, 32-37 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 32-33, 35-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Mayne et al, of record.

Mayne et al. disclose that HIV-1 protein Tat is neurotoxic and increases macrophage and microglia production of TNF-α, a cytopathic cytokine linked to the neuropathogenesis of HIV dementia (abstract). Mayne et al. further discloses that apoptotic and necrotic neuronal cell death associated with HIV dementia appears to be caused by indirect mechanisms induced by HIV proteins including increases in levels of $[Ca^{2+}]$. Furthermore, Mayne et al. concluded that Tat-induced increases in $[Ca^{2+}]$ were inhibited significantly by XeC (pg. 6541, left col. 2nd and 3rd paragraphs) at 1 μM concentrations (Figure 2).

Applicants' attention is directed to Ex parte Novitski, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such utility. In the instant application, as in Ex parte Novitski, supra, the claims are directed to preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

Arguments that such protective use is not set forth haec verba are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. On page 1391, Ex parte Novitski, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the

specification." In re Winkhaus, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Response to Arguments

Applicant argues that the Mayne et al. reference is concerned exclusively with examining calcium regulation in neurons. The only link to HIV is the use of a specific HIV coat protein, which is known to induce intracellular calcium release.

The Declaration under 37 CFR 1.132 filed 11/1/2006 is insufficient to overcome the rejection of claims 6, 32-33, 35-37 based upon Mayne et al. as set forth in the last Office action because Applicant's arguments do not rebut the fact that XeC was administered to patients infected with HIV. The motivation to reduce calcium release is because Mayne et al. clearly discloses the relationship between elevated calcium levels and the onset of HIV dementia.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Applicant argues that Mayne et al. does not teach or suggest that XeC could be used to treat an HIV infection, wherein the infection is treated by reducing viral particle load or viral particle assembly. Examiner views this limitation as inherent because this is simply a natural biological reaction of administration of the same compound (XeC) to the same population at the same dosage.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable

weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant's arguments herein are related to the mechanism of action of an agent in the treatment. Note that the mechanism of action of an agent in the treatment, by itself, does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated, and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompasses by the claims.

Applicant also argues that prior art teachings regarding the properties of XeC in fact teaches against the use of XeC in a pharmaceutical composition in the Mayne et al.

reference. This argument is not persuasive because the rejection is a 35 USC 102 rejection is anticipatory therefore a statutory bar.

Applicant further argues that treating HIV dementia is not the same as treating HIV infection. This argument is not persuasive because as admitted by the applicants, HIV dementia affects at least 5-10% of the AIDS sufferers, which are individuals infected with HIV (pg. 6, paragraph 3). Thus, treating HIV dementia is inherently treating HIV infection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 32-33, 35-37 are rejected under 35 U.S.C. 9 103 as being unpatentable over Pettit et al and Stingl et al, in view of DeBarieri et al.

Pettit et al and Stingl et al teach the claimed xestospongin D and xestospongin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These compounds were administered at dosages between 0.0006 micrograms per milliliter and 25 micrograms per milliliter, encompassing those dosage ranges herein recited. These medicaments are taught as broadly useful for treating retroviral infections (murine P388 lymphocytic leukemia and L1210) respectively DeBarbieri et al teach P388 cancer cells and 11210 cancer cells as having a retroviral etiology, and agents treating these retro-viral etiological agents treat these neoplastic conditions (see column 5, line 59 to column 6, line 13, and figures 13-15). The use of various xestospongin compounds to treat retroviral infections broadly in P388 cells and 11210 cells would have been viewed by the skilled artisan as treating retroviral infections generally.

Claims 6 and 32-33, and the primary references, differ as to:

1) employment of these medicaments to treat HIV infections and

2) administration of the specific medicaments.

Possessing these teachings of effective anti-retroviral therapy for two distinct retroviral etiological agents employing various xestospongin compounds would have motivated the skilled artisan to administer the instant xestospongin compounds, which are taught as possessing broad anti-retroviral activity, to treat all retroviral diseases', absent information to the contrary. This broad antiretroviral activity possessed by the prior art xestospongin compounds would have motivated the skilled artisan to employ

these compounds, and related compounds to treat retro-viral infections broadly, and enjoy a reasonable expectation of effectively treating HIV.

The skilled artisan, possessing a compound for an old and well known therapeutic use possesses that compounds isomers, analogs, homologs, bioisosteres for the same use. Attention is directed to In re Ward 141 USPQ 227 (CCPA 1964) and Galaxo Operations U.K. Ltd. V. Quigg 13 USPQ2d 1628, setting forth guidelines regarding therapeutic compounds relationships. Those compounds taught as obvious over the therapeutic compound are isomers, analogs, homologs and bioisosteres. In the instant case, Applicants attempt to capture these obvious variants of the old and well known antiretroviral xestospongin therapeutic compounds.

Absent an illustration of unexpected benefits residing in the specific compounds herein claimed, the instant claims remain properly rejected under 35 USC 103.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Absent information to the contrary, the skilled artisan would have seen the selection of one or another conventional administration route as the simple selection between obvious alternatives. Possessing the examiner cited teachings, the skilled artisan would have been motivated to employ the claimed active ingredients to treat neurological alchemic conditions, in the manner recited in the instant claims, absent information to the contrary.

Claim 34 is rejected under 35 U.S.C. 1 103 as being unpatentable over Pettit et al and Stingl et al, in view of DeBarieri et al, as set forth above for claims 6, 32-33, 35-37 in further view of Rideout et al.

Pettit et al and Stingl et al teach the claimed xestospongin D and xestospongin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These compounds were administered at dosages between 0.0006 micrograms per milliliter and 25 micrograms per milliliter, encompassing those dosage ranges herein recited. These medicaments are taught as useful for treating retroviral infections (murine P388 lymphocytic leukemia and L1210 leukemia) respectively, viewed by the skilled artisan as treating retroviral infections generally.

Claim 34, and the primary references, differ as to:

1) concomitant employment of these medicaments to treat HIV infections.

Attention is directed to Rideout et al teaching AZT as old and well known for treating HIV infections.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant

use of two conventional anti-viral agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Response to Arguments

Applicant argues while structurally related, the actions of XeC and XeD and XeF have not been shown to be equivalent.

It is well settled in patent law that the selection of a known material based on its suitability for its intended use is *prima facie* obvious. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). What's more, the *prima facie* obviousness is also supported by the holding that homologs are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Applicant also argues that not all retroviruses behave in a similar manner and not all retroviruses require NF-kB. This is not persuasive because the standard for obviousness is not absolute but a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER